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VESPER1

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1  
2 RECORD OF ORAL HEARING  
3 UNITED STATES PATENT AND TRADEMARK OFFICE

4  
5 BEFORE THE BOARD OF PATENT APPEALS  
6 AND INTERFERENCES  
7

8 *Ex parte* STEPHEN JOSEPH VESPER  
9

10 Appeal 2009-006220  
11 Application No. 09/866,793  
12 Technology Center 1600  
13

14 Oral Hearing Held: January 14, 2010  
15  
16  
17

18 Before TONI R. SCHEINER, DEMETRA J. MILLS, and  
19 FRANCISCO C. PRATS, Administrative Patent Judges  
20

21 ON BEHALF OF THE APPELLANTS:  
22

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1           The above-entitled matter came on for hearing on Thursday,  
2   January 14, 2010, commencing at 9:20 a.m., at the U.S. Patent and  
3   Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Kevin E.  
4   Carr, Notary Public.

5           THE USHER: Calendar number 46, Appeal number  
6   2009-006220.

7           Ms. Kornbau.

8           JUDGE SCHEINER: Thank you. Good morning.

9           MS. KORNBAU: Good morning. May it please the board, I'm  
10   Anne Kornbau, and with me are Laura Scalise and Randall Cherry. We  
11   represent the Appellant, Stephen Vesper and the assignee, the United States  
12   Environmental Protection Agency.

13          JUDGE SCHEINER: Before I forget, because I keep  
14   forgetting, do you have a business card for our reporter, please?

15          MS. KORNBAU: Sure.

16          JUDGE SCHEINER: Thank you.

17          MS. KORNBAU: This is the first time I've been asked for that  
18   at an appeal.

19          JUDGE SCHEINER: Well, everything is on the record now,  
20   so -- well, whenever you're ready.

21          MS. KORNBAU: I'm sorry?

22          JUDGE SCHEINER: We're ready whenever you are.

23          MS. KORNBAU: Okay, thank you. I'm sure you're familiar  
24   with the problem of sick building syndrome. This is one of the problems the  
25   EPA has been working on solving. It really is often caused by molds that  
26   get into the buildings, molds and fungi, which are very difficult to eradicate,

1 and also to identify. What the inventor here has done has come with -- has  
2 found that there are markers that can be used for these organisms, the ones  
3 that produce hemolysins. Not all fungi or molds do produce hemolysins.  
4 But the ones that do, produce hemolysins that are specific to that particular  
5 organism.

6               So what he has done is -- because animals who are infected  
7 with these hemolysins do not produce antibodies to the hemolysins, he's  
8 attached antibodies -- labeled antibodies to use -- to check for people who  
9 might have been exposed to these hemolysin producing organisms. Also, he  
10 can -- if a building has been infected with these organisms, he can take a  
11 sample of whatever seems to be the problem, if there's some black mold or  
12 whatever, and determine if the building is infected, and if -- with what  
13 organism the building has been infected.

14              The reference that the Examiner is relying upon, Sakaguchi,  
15 was published in 1984. And what Sakaguchi was doing was he was  
16 checking how the hemolysin went through the body of the mouse. He knew  
17 that he had injected hemolysin into the mouse and he was trying to see  
18 where it was going, how it would -- which tissues would be infected.  
19 Evidently what they were looking for was a way to attack cholesterol that  
20 would be less damaging than it -- than the drugs that were already on the  
21 market. So, 1984. Yes, there was a hemolysin and antibody assay, but  
22 nobody did anything more with it.

23              It was this particular inventor who discovered that there are  
24 these markers for specific organisms that can be used to determine if a  
25 person or an animal has been exposed to a specific organism. And it's not  
26 the concept of just the immunoassay, because that's well known in the art.

1 What he has done is found these markers and has made the mark -- has made  
2 use of these markers to identify if someone has been affected with -- has  
3 been exposed to the organism or if the building is infected with it.

4 JUDGE SCHEINER: Now isn't this one of the main points of  
5 contention in this case, is that the Examiner's position is that you don't have  
6 written descriptive support for looking at specific markers, versus any -- a  
7 marker of any hemolysin that would detect any mold that produces that  
8 enzyme?

9 MS. KORNBAU: Well, what -- I think the problem here is we  
10 don't have the exact language in haec verba. But we do -- I mean, why  
11 would you look for specific organisms if they don't produce a hemolysin  
12 that's specific to that organism?

13 JUDGE SCHEINER: Well, isn't that the question? Are you  
14 just looking for any, any mold that produces that, or do you -- or was the  
15 focus of the invention on determining which specific mold, or which specific  
16 organism you were dealing with?

17 MS. KORNBAU: We were looking for specific organisms.  
18 Because I think if we were only looking for organisms producing  
19 hemolysins, that's already been done, I mean, for one particular organism  
20 that produced a hemolysin.

21 JUDGE SCHEINER: In other words, in that -- if that were the  
22 case, you would just do the agar. You would just do the sheep blood assay.

23 MS. KORNBAU: Right. But this way, you can predict or you  
24 can determine which micro -- which organism you have a problem with.  
25 You know, if someone has respiratory problems from a sick building, you  
26 can determine -- take a blood sample, saliva sample and determine which

1 organism has infected that person. Or if the person doesn't show any  
2 symptoms, then --

3 JUDGE SCHEINER: Is that significant for treatment? Do you  
4 need to know specifically which organism you have? I mean, is that  
5 discussed anywhere in the --

6 MS. KORNBAU: It's -- because you have to design the  
7 treatment, or treating the building, which organisms are infecting the  
8 building. Some of them cannot be killed. You just have to take it all down.  
9 But if there's one that can be dealt with, say by spraying chlorine on it, it's a  
10 lot better than taking down the building.

11 JUDGE SCHEINER: Okay. Well, why don't we focus on each  
12 rejection as -- let's take them in turn and --

13 MS. KORNBAU: Okay. Well, I think with Sakaguchi, the 103  
14 rejection, this was done in 1984. He knew that he was infecting the mouse,  
15 and what he was doing was tracking the progress of the hemolysin through  
16 the mouse's organs. We don't know if someone has been exposed to an  
17 organism like this. So we can check to see if -- does this person have an  
18 allergy, or is it really exposure to a particular organism that's causing the  
19 respiratory problems, for example. The fact that Sakaguchi did it in '84 and  
20 no one has come up with these markers for these organisms would lead me  
21 to believe that maybe there is something unobvious here. There is also an  
22 exclusive license on this application, so obviously it has commercial value.

23 JUDGE SCHEINER: So then the next -- we have -- let's see.  
24 We have the -- all right. Now it's our understanding that your position on  
25 the 103 then is that Sakaguchi knew that the animal had been exposed, and  
26 therefore you don't have an unknown?

1 MS. KORNBAU: Well, he --

2 JUDGE SCHEINER: Or an animal of unknown -- or a  
3 building of unknown status.

4 MS. KORNBAU: Right.

5 JUDGE SCHEINER: So then we also have a -- isn't there a  
6 102 for --

7 JUDGE PRATS: I believe there is a 102 over claim 33.

8 JUDGE SCHEINER: There are a lot of rejections in this case  
9 so --

10 MS. KORNBAU: I know.

11 JUDGE SCHEINER: Trying to figure out the best way to go  
12 through them, step-wise.

13 MS. KORNBAU: Well, again, a method for determining if an  
14 animal has been exposed. And I think this where the preamble of the claim  
15 puts limitations into it. We're not just assaying for hemolysin. What we're  
16 doing is we are determining if an animal has been exposed to one of these  
17 organisms.

18 JUDGE PRATS: So you're saying essentially that the preamble  
19 of the claims requires the subject to be an unknown.

20 MS. KORNBAU: Right, because we're determining if.  
21 Whereas Sakaguchi knew that the animal had been injected with the  
22 hemolysin.

23 JUDGE PRATS: Right. But arguably one of  
24 ordinary -- wouldn't one of ordinary skill in the art reading Sakaguchi  
25 recognize that, "Hey, I can tell if somebody's been exposed to this by  
26 assaying for the hemolysin."

1 MS. KORNBAU: Why did nobody do it for 20 years? I mean,  
2 people have been concerned about the mold in the buildings and the  
3 exposure to mold for long time. And also, Sakaguchi only used that one  
4 hemolysin. Vesper, Doctor Vesper has discovered that there are -- not all  
5 fungi produce hemolysins. But the ones that do, the hemolysins are specific.  
6 And in his Declaration that was filed in I believe 2005 he showed how very,  
7 very simple it is to extract the hemolysin from a number of different  
8 organisms.

9 JUDGE PRATS: Right. But with respect to Sakaguchi isn't  
10 that -- I mean, the hemolysin there meets the requirement that it's species  
11 specific, correct?

12 MS. KORNBAU: We didn't know that, because he knew that  
13 he had the Aspergillus and he had the hemolysin for that. There's nothing in  
14 Sakaguchi that even suggests that this can be used for different types of  
15 organisms. I mean, there's a big difference between knowingly injecting the  
16 stuff and tracking it through the tissues, from knowing that there are lots of  
17 these organisms that produce hemolysins and one can detect them. The  
18 animals do not produce antibodies to hemolysins so you can't just do a  
19 standard immunoassay. You have to -- as the inventor has, excuse me,  
20 pointed out, you have to tag it to an antibody and then --

21 JUDGE PRATS: Right. But there seems to be a distinction  
22 between the 102 and the 103 here, in that you necessarily have to have an  
23 unknown. One could argue that, you know, Sakaguchi doesn't have an  
24 unknown. But with respect to the 103, you could argue the take home  
25 message is that you can assay an unknown for exposure by looking for



1 hemolysin -- this hemolysin right here, which is inherently species specific,  
2 correct?

3 MS. KORNBAU: We don't know from Sakaguchi that it's  
4 species specific.

5 JUDGE PRATS: But do you need to know that to conduct the  
6 assay that's suggested -- that's arguably suggested by that reference?

7 MS. KORNBAU: You need to know that so you  
8 know -- because what we're doing to determine if someone's been exposed to  
9 such an organism, and because they each have specific hemolysins, one can  
10 determine which organism has been infecting the person or the building.

11 JUDGE PRATS: So you don't think that Sakaguchi suggests  
12 that detecting for the ASP hemolysin suggests that you'd be able to detect  
13 exposure to a fumigatus then?

14 MS. KORNBAU: No, because there's nothing in Sakaguchi  
15 other than here we injected the mouse with this stuff and we detected it.  
16 We -- not so much detected it, but tracked it through the body.

17 JUDGE PRATS: Thank you.

18 MS. KORNBAU: You're welcome. Shall we go on to the  
19 written description --

20 JUDGE PRATS: Sure.

21 JUDGE SCHEINER: Please.

22 MS. KORNBAU: Okay. again, with species specific, I think  
23 the Examiner is looking for the exact words. And we know that you don't  
24 have to have the exact words, but someone skilled in the art reading this  
25 would say, "Oh, you can detect this, you can detect this, because they have  
26 specific hemolysins." I think there was some question about species versus

1 strains, which is why I'm calling them organisms. Because it turns out that  
2 fungi have their own kingdom, so we don't want to get into the classification  
3 of these, so I'm calling them organisms. But they are -- the hemolysin is  
4 specific for each organism, which is why this test, this marker is so useful  
5 and why it has been licensed exclusively by a very large company. It's a  
6 very useful test. It's the only test available right now, other than, you know,  
7 just the auger. And this way you can find out what you have, and it's  
8 reasonably inexpensive and rapid.

9 JUDGE MILLS: What language did the specification use when  
10 it described the organisms? Didn't it use strains?

11 MS. KORNBAU: It used strains, right. But --

12 JUDGE MILLS: And how would one of ordinary skill in the  
13 art view a strain as compared to a species?

14 MS. KORNBAU: Well, what --

15 JUDGE MILLS: And do we have any evidence of record  
16 showing that they're the same?

17 MS. KORNBAU: One of the problems -- I was speaking with  
18 the inventor yesterday -- Tuesday. And he said that there is -- with  
19 classification, he said there are a lot of interchangeable -- people use the  
20 terms interchangeably. And that's why I'm -- for this -- for the purposes of  
21 this argument, it's a specific organism. I don't want to get into the species  
22 and strains, because the specific organism you're looking for is producing a  
23 hemolysin that is specific to that particular organism. And that's -- that's the  
24 whole point of the test, that if you have specific hemolysins produced by  
25 individual organisms then you can analyze for that hemolysin and say, "Yes,  
26 this organism is present, or this organism is not present."

1 JUDGE SCHEINER: Is there any place in your specification  
2 where you -- where the inventors raise antibody against hemolysins from  
3 different organisms, strains, species, whatever, and show that they're specific  
4 for that molecule?

5 MS. KORNBAU: Well, you can't raise antibodies to the  
6 hemolysins. That's the problem.

7 JUDGE SCHEINER: No, no, no. I mean, detect them one  
8 from the other.

9 MS. KORNBAU: Okay. I don't think we have specific  
10 examples.

11 JUDGE SCHEINER: Well, according to -- I'm looking at page  
12 11 of the specification. It's -- there's a prophetic discussion that once you  
13 have the amino acid sequence, once you've deduced it from the DNA, then  
14 you can synthesize fragments.

15 MS. KORNBAU: Right.

16 JUDGE SCHEINER: And that those fragments contain  
17 immunoreactive portions attached to sequences designed to provide for some  
18 additional property. I'm just looking to see if there is anything in the  
19 specification where the technique for detecting one organism versus another  
20 is discussed. So far what I'm seeing is pretty generic.

21 MS. SCALISE: Paragraph 24?

22 MS. KORNBAU: Excuse me?

23 MS. SCALISE: Paragraph 24.

24 MS. KORNBAU: Paragraph 24 was --

25 JUDGE SCHEINER: Twenty-four? Okay.

26 MS. KORNBAU: Yeah.

1 JUDGE SCHEINER: Okay. All right. Let's take a look.

2 MS. KORNBAU: By growing strains of hemolysin producing  
3 fungi in vitro and isolating the hemolysin, it's now possible to use the protein  
4 obtained to identify fungi which are isolated from buildings, homes, schools  
5 and the like. The fungal strains are grown in a conventional -- but if you're  
6 identifying them, it's not saying this is a fungus. It's identifying the specific  
7 one.

8 JUDGE SCHEINER: To me it looks like it's saying you're  
9 identifying hemolysin producing fungi, fungi, as a -- it could be interpreted  
10 that way, as a group.

11 MS. KORNBAU: But we interpreted it differently because  
12 obviously we're looking for different strains of fungi, or different organisms.  
13 Let's put it that way. I don't want to get into the classification.

14 JUDGE SCHEINER: Right, right. Okay. Well, why don't we  
15 move on? We still have a few rejections to --

16 MS. KORNBAU: Okay. Okay, claims 30 to 32. Oh, for  
17 determining if an animal has been exposed to a particular fungus. Okay.  
18 The method for determining an animal has been exposed to a particular  
19 fungus is contacting the sample with the labeled antibody. One skilled in the  
20 art can certainly extrapolate from this method in which the hemolysin has  
21 been obtained from the building. I don't see where there's any problem.  
22 This is -- the assays themselves are well known in the art. It's -- the whole  
23 concept that's important is the fact that we've discovered that there are these  
24 markers that can be used to assay for individual specific hemolysin  
25 producing organisms. And to put in every little step of the assay I think is  
26 insulting to one skilled in the art.

1 JUDGE SCHEINER: I don't think that's what the Examiner  
2 was asking for, but --

3 JUDGE PRATS: Well, is the distinction actually between  
4 what's possessed in the spec, and the Examiner wants it literally laid out  
5 word for word? Is that what you're saying?

6 MS. KORNBAU: That's what I'm saying. I think she's looking  
7 for every single little step that one skilled in the art certainly would be able  
8 to -- to put in there. I'm not -- I'm a chemist, but I can understand this. I can  
9 understand the basic steps of what they're doing, because a lot of these  
10 assays are well -- the techniques for the assays are well known in the art.  
11 People have been doing immunoassays for what, 40 years? So I think she's  
12 looking for more than is necessary. And I think the rejection of 23 to 26 is  
13 failing to comply with the written description requirement. They have to be  
14 species specific or organism specific, or there would be no point in filing  
15 this patent application. We have these markers. The big deal is we found  
16 that there are these markers for individual organisms that can be used to  
17 determine exposure or presence of.

18 JUDGE PRATS: Now the -- you're talking about the next to  
19 last rejection over claims 23 to 26.

20 MS. KORNBAU: Mm-hmm.

21 JUDGE PRATS: It looks like the rationale is pretty much the  
22 same as the previous written description over 23 to 26 and 29.

23 MS. KORNBAU: Mm-hmm.

24 JUDGE PRATS: Does that sound right?

25 MS. KORNBAU: That sounds right.

1 JUDGE PRATS: And it sounds like it's almost the same  
2 rejection, just restated.

3 MS. KORNBAU: Just -- she's worded it differently.

4 JUDGE PRATS: Yeah.

5 MS. KORNBAU: I think what she was looking for is the exact  
6 wording, and as you know we don't have to have the exact wording. If one  
7 skilled in the art can understand that this is what was going on, that's  
8 enough. And if a non-immunologist or a non-microbiologist can understand  
9 this, one skilled in the art certainly could understand what the inventors had  
10 here.

11 So I think the written description rejections are all about the  
12 same, and can be answered basically the same way. We've explained what  
13 we're doing, how to do it. One skilled in the art can run these assays with no  
14 trouble at all. Once you've tagged the hemolysin with the antibody, it's a  
15 fairly straightforward procedure. The invention here was discovering that  
16 there are these markers that can be used for such assays.

17 JUDGE SCHEINER: Were there any rejections that we haven't  
18 covered yet?

19 JUDGE PRATS: There's a 112 second. It was the last  
20 rejection, I think.

21 JUDGE SCHEINER: Oh.

22 MS. KORNBAU: Oh, because all of the steps for determining  
23 if a building contains the hemolysin producing organism -- once again, I  
24 think this is so straightforward that one skilled in the art would be able  
25 to -- it's -- you obtain a sample. You obtain the hemolysin from the sample.  
26 It's very simple to -- we disclose how to obtain the hemolysin from the

1 sample. You contact it with labeled antibodies to the hemolysin and detect if  
2 there is any complex formed. That seems pretty straightforward to me. And  
3 I don't think there are any steps missing. I mean, I can certainly -- we've  
4 disclosed how to obtain the hemolysin. Again, that's not rocket science. It's  
5 something that has been disclosed, one skilled in the art can readily do.  
6 Why put all of those little steps into the claim? There might be better ways  
7 that someone finds later on, and so it wouldn't be right to restrict the claim to  
8 those specific steps of obtaining the hemolysin.

9 JUDGE SCHEINER: Did you have anything further?

10 JUDGE MILLS: No. I don't have any questions.

11 JUDGE SCHEINER: I think we've asked all our questions. If  
12 you've -- unless you have anything further, I think we understand the issues.

13 MS. KORNBAU: No. I just wanted really to answer your  
14 questions.

15 JUDGE SCHEINER: Okay.

16 MS. KORNBAU: Thank you very much.

17 JUDGE SCHEINER: All right. Thank you for coming in.

18 Whereupon, at 9:44 a.m., the proceedings were concluded.

19